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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,640	02/19/2004	Taro Aoki	249160US0X	1883

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,640	AOKI ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-10* is/are rejected.

7)☒ Claim(s) *7-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

CLAIMS 1-3 AND 5-10 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statements filed December 8, 2004 and February 15, 2005 and Amendment filed February 15, 2005 have been received and entered into the application.

Accordingly, claims 1-3, 5 and 6 have been amended; claim 4 has been canceled; and claims 7-10 have been added. Also, as reflected by the attached, completed copies of "Form PTO 1449 (Modified)", (2 pages), the Examiner has considered the cited references.

In view of the above amendments, the claim/specification objection and rejection of claims 1-3, 5 and 6 under 35 U.S.C. § 112, second paragraph, as set forth in the previous Office action dated October 21, 2004, are withdrawn.

References Newly Cited by the Examiner

The references cited on the attached form PTO-892 have not been relied on and are included to show the general state of the art.

Claim Objections

Claims 7-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The recitation of "A blood triglyceride-decreasing agent" fails to impart any further material feature to the composition, i.e., "agent", of claims 7-9 over that which is set forth in claims 1-3. It is recommended that Applicants cancel claims 7-9 in order to overcome the present objection.

Claim 10 is objected to because "eicosapaenoate" should read ---eicosapentaenoate---.

Claim Rejection - 35 USC § 103

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (Int. J. Clin Lab. Res. reference cited by applicants; see IDS filed May 26, 2004)) in view of applicants' acknowledgement at page 4, line 13 – page 5, line 1 of the specification and Fujikawa et al. (U.S. Patent No. 5,856,336), each of record, for the reasons of record as set forth in the previous Office action dated October 21, 2004 at pages 3-4, as applied to claims 1-3, 5 and 6.

Newly added claims 7-10 are properly included because claims 7-9 merely entitle the previously considered agent of claims 1-3 as a "blood triglyceride-decreasing agent" and do not provide for a material feature of the agent that was not previously considered. Claim 10 requires that the pitavastatin is the pitavastatin calcium and that the eicosapentaenoic or ester thereof is ethyl eicosapentaenoate. These requirements appeared in previously presented claims 2 and 3.

Applicants' remarks at pages 6-9 of their Amendment, as well as the data illustrated in Figure 1 of the present specification, have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Applicants have argued that the teachings of Nakamura et al. are limited to only two specific HMG-CoA reductase inhibitors and such is insufficient to support a conclusion that HMG-CoA reductase inhibitors, as a class, would have the same characteristics as the specifically identified inhibitors. Thus, at page 6 of their amendment, Applicants have stated "It is evident therefore that the Nakamura reference to the class of 'HGM-CoA reductase inhibitors' [sic] is based on a disclosure of just two such inhibitors. That constitutes an insufficient basis upon which to support a generalization relating to the characteristics of the entire class."

(emphasis original). Also, at page 7, last paragraph of the Amendment, Applicants have further urged that pitavastatin is chemically distinct from the HMG-CoA reductase inhibitors in Nakamura et al. and that such further supports their position stated above.

The Examiner disagrees and believes that the disclosure of Nakamura et al., as relied on by the Examiner (see the previous Office action at page 4, lines 1-2 "see the abstract, page 22, col. 2, third paragraph under 'Introduction' and page 24, the entire section under 'Discussion'"), is reasonably sufficient to support a conclusion as to the activity that would have been expected by one of ordinary skill in the art for HMG-CoA reductase inhibitors as a class.

Applicants have also argued that that based on the teachings of Nakamura et al., there would be no basis for concluding that an unexpected result is achievable by "a combination of the specific reductase inhibitors (here recited and not disclosed by Nakamura) of Fujikawa et al. with EPA ester or equivalent." (Amendment at page 7). Such an expectation, however, is not required for a finding of obviousness. All that is required is a basis for concluding that the claimed subject matter would have been would have been suggested to one of ordinary skill in the art. The Examiner believes that the references provide a sound basis for such a conclusion.

As stated by the Examiner in the previous Office action at page 4, the data in the present specification at pages 8-10 have been considered, "but fail to diminish the propriety of the present rejection because (a) the conclusion that the results are 'synergistic' is not factually supported, (b) it has not been explained what the skilled artisan would have expected from such a combination and (c) the criticalness of using pitavastatin has not been demonstrated, i.e., the testing of different HMG-CoA reductase inhibitors, that the results obtained by Applicants are any different than would have been expected given the teachings and data of Nakamura et al.".

Applicants have urged that the results are synergistic. Applicants have further pointed out that the presented data is of statistical significance. The Examiner accepts that the data is of statistical significance. However, the data demonstrated in Figure 1 apparently shows no more than additive results. That is, if one considers the results demonstrated for pitavastatin and EPA alone, the results shown for the combination do not appear to show that an unexpectedly lower triglyceride level is obtained. As stated in the MPEP at section 716.02(b)(II), "'[A]ppellants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness.' *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992).". Also, the data is specific to anti-triglyceride activity and it is not seen that such is commensurate in scope with the claimed subject matter, i.e., the claimed method is directed to treating "hyperlipemia" in general. Also, the results of Applicants are realized only by carrying forth certain method steps. Even if it is established that Applicants' data show results that would not have been expected, it is not believed that such supports a conclusion that the claimed compositions, which are not patentably limited by statements of intended use or function and which are static entities, i.e., method steps are not required elements of a composition, would not have been obvious.

In response to (b), above, Applicants have stated that "The implied requirement that Applicant explain what the skilled artisan would have expected from the combination assumes the prior art explicitly suggests the combination, which is not in fact the case." (Amendment at page 7). Applicants should, however, provide an explanation of their data. Data have been shown by Applicants for a tested combination of compounds and it remains that Applicants have not explained how the data show results which should support a conclusion of nonobviousness.

Respecting (c), above, Applicants have urged that "the requirement that [they] carry out extensive testing procedure would appear to be unjustified for the reason again that the Official Action reads more into the Nakamura et al. disclosure than is present there." (emphasis original, Amendment at page 7). The Examiner has reconsidered and withdraws his position that Applicants should show results when different HMG-CoA reductase inhibitors are employed in combination with EPA. The data in Nakamura et al., i.e., described and shown at page 23, appear to establish what one of ordinary skill in the art would have reasonably expected from a treatment method which involves the administration of a combination of EPA and an HMG-CoA reductase inhibitor. In particular, that a combination of a HMG-CoA reductase inhibitor and EPA is effective for lowering serum triglyceride levels (see page 23, Tables 1-2). Applicants' data, however, does not appear to be inconsistent therewith in that as compared to treatment with an HMG-CoA reductase inhibitor alone, a combination of the HMG-CoA reductase inhibitor and EPA provided a greater serum triglyceride-lowering effect.

At page 8, last paragraph of their amendment, Applicants have stated "...it should be noted that there is no data in Nakamura showing the effect of sole administration of statin or EPA, such data being necessary to judge whether any synergic [sic] effect of using both components exists or not.". The data of Nakamura et al. do show, however, results for the statin compound alone (Table 1) and that when combined with EPA treatment, significantly lower serum triglyceride levels resulted. Such results are not seen to be inconsistent with Applicants' data and are supportive of the Examiner's conclusion of obviousness.

Also, Applicants have argued that the compounds of Fujikawa et al. "are sufficiently different from those of Nakamura et al. that their generalizations extended to include them are

clearly speculative". The Examiner cannot concur because of the functional relationship that would have been appreciated for the compounds of Fujikawa et al. and those of Nakamura et al., i.e., they share the common feature of being HMG-CoA reductase inhibitors. Fujikawa et al. establish pitavastatin to have been a known HMG-CoA reductase inhibitor and as such, supports the Examiner's conclusion of obviousness.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

April 16, 2005